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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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CLARK & ELBING, LLP
176 FEDERAL STREET
BOSTON, MA 021102214

EXAMINER
EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
1644	34

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/756,018	Applicant(s) Seed et al.
	Examiner G. R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 24, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *10, 12-14, 24, and 25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *10, 12-14, 24, and 25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Claims 10, 12-14, and 24-25 are pending.

2. In view of Applicant's amendment and response, filed 9/24/01, all rejections under the second paragraph of 35 U.S.C. 112 have been withdrawn. Only the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 31, mailed 3/21/01.

Applicant's arguments, filed 9/24/01, have been fully considered but they are not persuasive. First note that Applicant has inaccurately paraphrased the previous Office action. Said action *did not* state that "The Office further asserts that the exemplary P-selectin ligand disclosed in the specification works only in an *in vitro* binding assay while the invention has only *in vivo* therapeutic and diagnostic uses," as Applicant asserts. The action actually states that the specification provides just a single *in vitro* assay while disclosing only *in vivo* therapeutic and diagnostic uses. Applicant is reminded that the Office does not have the facilities to ascertain the conditions under which any given invention functions and relies solely on the disclosures of the specifications and the relevant prior art. Thus, the Office is unlikely to hold a position that an invention works only under certain conditions, but rather the Office is more likely to hold a position that the specification discloses only that an invention has been demonstrated to function under certain conditions. These are significantly different positions. In the instant case the specification discloses just a single *in vitro* assay (HL-60 cell rolling) while the only specific disclosed intended uses are *in vivo* (see Use, page 30-32).

Applicant argues that the teachings of the prior art are irrelevant "because the prevailing belief as to the strict structural requirements required for an active P-selectin ligand was incorrect," and that "In view of this discovery, applicants submit that it is, in fact, quite predictable that other P-selectin ligands can be produced using the information provided in the specification, in combination with only routine experimentation." It is the Examiner's position, however, that the correctness or incorrectness of the prior art notwithstanding, Applicant's disclosure of a single polypeptide in support of the broad genus encompassed by Claim 10 is insufficient support that additional polypeptides could be made without undue experimentation. Applicant further argues (in a section entitled *Nucleic Acid and Protein Design*) that sialyl Le^x addition sites are well known and tyrosine sulfation sites are well characterized by "**five simple rules**." However, it is noted that Applicant's "**five simple rules**" still encompass an essentially unlimited number of tyrosine sulfation sites of which the specification discloses just one that functions in the claimed invention. Further, Applicant has not addressed the problem of the positioning of said sialyl Le^x addition sites and tyrosine sulfation sites in relation to one another. Thus, it is the Examiner's position that the disclosure of the specification remains insufficient to support the instant claims to an invention that would encompass an essentially unlimited number of polypeptides.

Applicant further argues that "a requirement for working examples is not supported by the law." It is the Examiner's position that, while working examples are not required, some sort of *in vivo* enablement is required, and working examples comprise the most common sort of *in vivo* enablement.

Applicant further argues that the diagnostic assays involving P-selectin ligands would typically be carried out *in vitro*, and not *in vivo*. However, the specification discloses "antibodies or antibody fusion proteins according to the invention may be used in conventional techniques of antibody-based therapies or *in vivo* diagnostics," (Use, page 31), thus indicating an *in vivo* intended use. Applicant further argues that the HL-60 rolling assay should be considered "an acceptable correlate for a ligand's efficacy in inhibiting inflammation-elated processes *in vivo*." However, it is the Examiner's position that the specification fails to establish sufficient correlation between said assay and any *in vivo* process, thus, said assay can not be considered a relevant *in vitro* model for any *in vivo* process.

5. Claims 10, 12-14, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper No. 31, mailed 3/21/01.

Applicant's arguments, filed 9/24/01, have been fully considered but they are not persuasive. Applicant argues that, the instant specification recites structural features common to the members of the claimed genus sufficient to describe said genus along with a working example. However, it is the Examiner's position that the two features (sialyl Le^x addition sites and tyrosine sulfation sites) could encompass an essentially unlimited number of polypeptides and that the specification additionally fails to disclose sufficient limitations with regards to the location of said sites in relation to one another. Thus, the single embodiment of the claimed genus is insufficient to adequately describe the claimed invention.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina

Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 5, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600